



Drug Enforcement Administration

[Docket No. DEA-974]

Bulk Manufacturer of Controlled Substances Application: Cedarburg Pharmaceuticals

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Cedarburg Pharmaceuticals has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: DEA requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <http://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.”

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on August 27, 2021, Cedarburg Pharmaceuticals, 870 Badger Circle, Grafton,

Wisconsin 53024-0000, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

| Controlled Substance | Drug Code | Schedule |
|---|------------------|-----------------|
| Lysergic Acid Diethylamide | 7315 | I |
| Tetrahydrocannabinols | 7370 | I |
| 4-Bromo-2,5-Dimethoxyphenethylamine | 7392 | I |
| 3,4-Methylenedioxyamphetamine | 7400 | I |
| 3,4-Methylenedioxymethamphetamine | 7405 | I |
| 5-Methoxy-N-N-dimethyltryptamine | 7431 | I |
| Dimethyltryptamine | 7435 | I |
| Psilocybin | 7437 | I |
| Psilocyn | 7438 | I |
| Methylphenidate | 1724 | II |
| Nabilone | 7379 | II |
| 4-Anilino-N-Phenethyl-4-Piperidine (ANPP) | 8333 | II |
| Fentanyl | 9801 | II |

The company plans to bulk manufacture the listed controlled substances for the internal use intermediates or for sale to its customers. In reference to the drug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture as synthetic. No other activity for this drug code is authorized for this registration.

Matthew J. Strait,
Deputy Assistant Administrator.